REMARKS

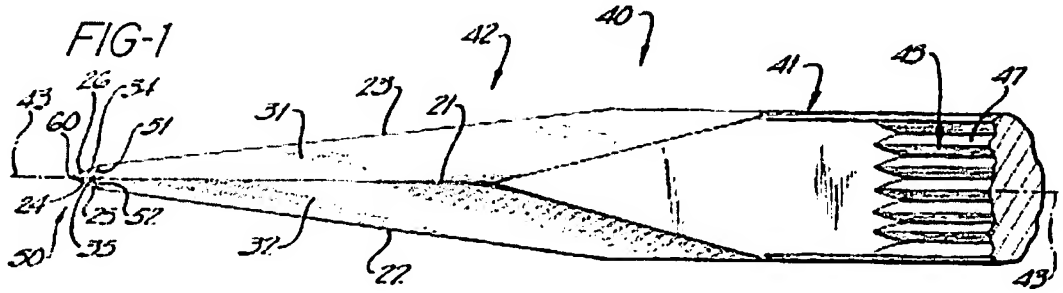
The above referenced application has been reviewed in light of the Final Office Action mailed May 27, 2010. Claims 2, 3, 10, 11, 13, 14, 16-20, and 22-25 are currently pending in this application with claims 20 and 23 being in independent form. In view of the remarks to follow, allowance of this application is respectfully requested.

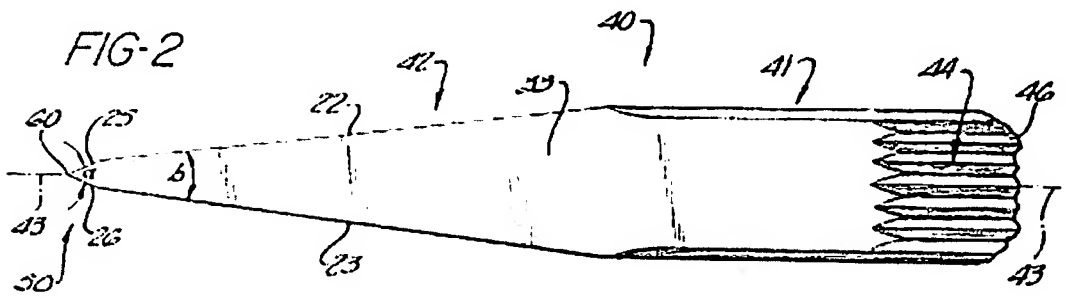
Claims 2-3, 10-11, 20, and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,513,747 to Smith et al. (hereinafter, "Smith") in view of U.S. Patent No. 5,464,422 to Silverman (hereinafter, "Silverman"), U.S. Patent No. 20,409 to Cottrill (hereinafter, "Cottrill"), and U.S. Patent No. 5,403,344 to Allen (hereinafter, "Allen"). Applicant respectfully submits that Smith in view of Silverman, Cottrill, and Allen, alone or in any proper combination, fail to teach or suggest the claimed surgical needles.

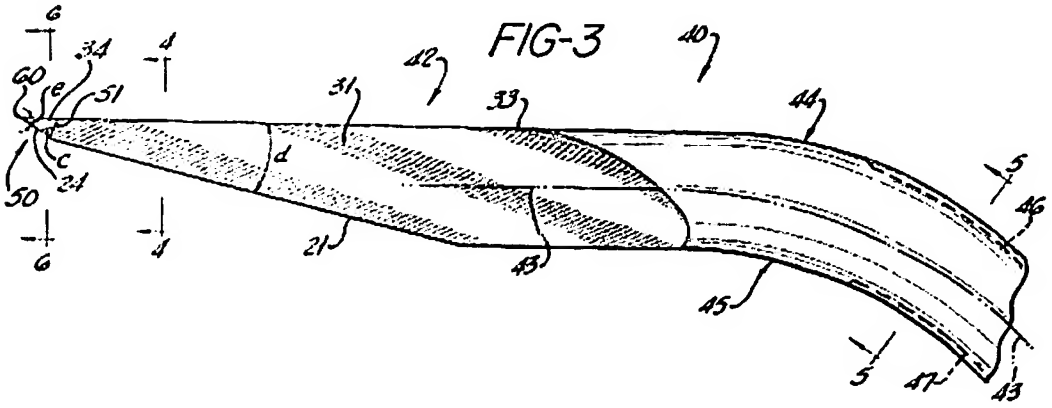
Smith relates to a surgical needle having one or more cutting edges converging towards the needle tip which are formed at the intersection of a plurality of planar surfaces. As illustrated in Figures 1-3 of Smith, reproduced hereinbelow, surgical needle 40 includes a cutting portion 42 including a main cutting edge 21 formed at the bottom of the cutting portion 42 by the intersection of planar surfaces 31 and 32 and secondary cutting edges 22 and 23 formed by the intersection of a third planar surface 33 (located on the top of the cutting portion 42) with planar surfaces 31 and 32, respectively.

The cutting portion 42 includes an end portion 50 and a tip 60. Planar surfaces 34 and 35 are formed at the bottom of end portion 50 thereby creating three additional cutting edges 24, 25, and 26. "It will be noted that cutting edge 24 constitutes an extension of cutting edge 21 (FIG. 3) and said cutting edge 24 extends to the tip 60 which lies at the intersection of the reference plane and planar surface 33 (FIG. 2)." (Column 4, lines 54-58). Additional cutting

edges are formed by the intersection between surfaces 31 and 34 to form edge 51 and the intersection between surfaces 32 and 35 to form edge 52. No edge is disposed along extended surface 33 as shown below.







Accordingly, Smith fails to disclose or suggest a surgical needle including, *inter alia*, a needle end defining a generally diamond-shape in cross-section, the needle end including a first distinct set of four generally concave intersecting surfaces and the needle tip including a second distinct set of four generally concave intersecting surfaces, and cutting edges disposed along

each respective line of intersection of the first set of four surfaces of the needle end with the second set of four surfaces of the needle tip.

Moreover, Smith states "[a]lthough the preferred needle of the present invention is *triple edged* with three smaller additional cutting edges located at the tip, nevertheless *the invention includes needles formed with fewer than three edges*, and in which there are at least two additional intersecting planar surfaces at the tip portion, forming one or more additional cutting edges." (Column 2, lines 51-57, Emphasis added). Accordingly, Smith effectively teaches away from providing more than three cutting edges.

Furthermore, pages 3-4 of the Office Action states the deficiencies of Smith as follows:

> The device of Smith is not explicitly disclosed with the first and second sets having four sides symmetrically arranged about the longitudinal axis to form a diamond cross-section and means for attaching a suture.... The modified device of Smith in view of Silverman is not explicitly disclosed with the first and second sets being generally concave.... The modified device of Smith in view of Silverman et al and Cottrill is not explicitly disclosed with the needle end having a maximum cross-section dimension greater than a maximum cross-sectional dimension of the main shaft.

In an attempt to cure a portion of the deficiencies of Smith, the Office Action relies on Silverman asserting that Silverman discloses a needle having four sides symmetrically arranged about a longitudinal axis to form a diamond cross-section, and alleging that it would have been obvious to a person having ordinary skill in the art to modify the device of Smith to have first and second sets having four sides symmetrically arranged about the longitudinal axis to form a diamond cross-section in order to provide cutting edges around the circumference of the needle for more efficient cutting and penetration of tissue. Applicants respectfully disagree.

The burden of establishing a prima facie case of obviousness falls on the Examiner. Ex parte *Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish a prima facie case of obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, it is not sufficient to show that all the elements exist in the prior art, since a claimed invention composed of several elements may not be proved obvious merely by demonstrating each element was known, independently, in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* Specifically, there must be some articulated reasoning with a rational underpinning to support a conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and must be based on objective evidence of record. *In re Lee*, 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002).

Here, the proposed reasoning for combining the references is that one skilled in the art would have modified the device of Smith to have first and second sets having four sides symmetrically arranged about the longitudinal axis to form a diamond cross-section in order to provide cutting edges around the circumference of the needle for more efficient cutting and penetration of tissue. In particular, the Advisory Action states that "one of ordinary skill in the art would have found it obvious to modify the device of the device of Smith by providing each set of surfaces with four surfaces, as taught by Silverman, to provide cutting edges around the circumference of the needle for more efficient cutting and penetration of tissue." However, the Examiner has not pointed to any teaching in the reference that first and second sets of four sides

would provide for more efficient cutting and penetration of tissue. Furthermore, Smith provides cutting edges around the circumference of the needle and thus, it is not seen where it is suggested that four edges is more efficient at cutting and penetrating tissue than three edges.

Absent any teaching in one of the two applied references that more cutting edges would improve the efficiency of cutting and penetration of tissue, there is no rational underpinning to support a conclusion of obviousness.

Moreover, Silverman explicitly discloses that a "conical point portion of the surgical needle of the present invention achieves a strong, bur-resistant point offering both good strength and good piercing characteristics with corresponding low penetration forces" (Column 2, lines 5-8) and further states that the "[c]onical point portion 15 is of substantially round cross section adjacent to point 17. By substantially round cross section is meant a round or substantially rounded cross section *without any sharp, angular, or square edges*." (Col. 3, lines 19-22, Emphasis added). Accordingly, Silverman effectively teaches away from having cutting edges on the portion of the needle that is proximal to the needle point.

Thus, Silverman's disclosure to have a conical point portion without any sharp edges, in combination with Smith's disclosure that three or fewer cutting edges produces a sharp needle (See generally, columns 1 and 2 of Smith describing the prior art and objectives of his invention), fail to provide any motivation whatsoever to modify the needle of Smith to include two distinct sets of four generally concave intersecting surfaces and cutting edges disposed along each respective line of intersection of the first and second sets of four surfaces.

Obviousness is determined as a matter of foresight, not hindsight. Only Applicants' disclosure provides any suggestion to provide a surgical needle with the recited features. Where there is no rational underpinning in the references to support the Examiner's

rationale for combining the references in the manner necessary to arrive at the claimed subject matter, the Examiner is clearly using Applicants' disclosure as a blueprint for piecing together the prior art to defeat patentability, which is the essence of hindsight.

Cottrill and Allen fail to cure the deficiencies of Smith and Silverman as Cottrill is relied upon for the recitation of concave surfaces in a needle and Allen is relied upon for the recitation of a needle end defining a maximum cross-sectional dimension being greater than a maximum cross-sectional dimension of the main shaft. Cottrill and Allen do not teach or suggest any of the above-noted deficiencies of Smith and/or Silverman.

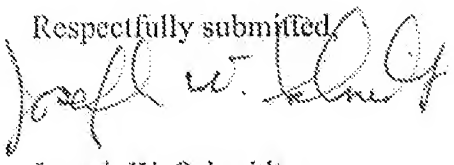
For at least these reasons, Applicants believe that independent claim 20 is patentable over Smith in view of Silverman, Cottrill, and Allen, taken alone or in any proper combination, and are in condition for allowance. For at least these reasons, inter alia, Applicants believe that claims 2, 3, 10, 11, and 22 which depend from claim 20, either directly or indirectly, also define over the cited references and are in condition for allowance.

Claims 13, 14, 16-19, and 23-25 stand rejected under 35 U.S.C. § 103(a) over Smith in view of Silverman and Cottrill. As stated above, Smith fails to show or suggest "respective cutting edges along each line of intersection of the first distinct set of at least three non-linear intersection surfaces with the second distinct set of at least three non-linear intersecting surfaces" as required by independent claim 23, and Silverman and Cottrill fail to cure the deficiencies of Smith as it is only with the use of the Applicants' own disclosure and impermissible hindsight that the Examiner is able to draw the conclusion that claim 23 is obvious over Smith in view of Silverman and Cottrill.

For at least these reasons, Applicants believe that independent claim 23 is patentable over Smith in view of Silverman and Cottrill, taken alone or in any proper combination, and are in condition for allowance. For at least these reasons, inter alia, Applicants believe that claims 13, 14, 16-19, 24, and 25 which depend from claim 23, either directly or indirectly, also define over the cited references and are in condition for allowance.

In view of the foregoing remarks, Applicant submits that all of the claims are in proper format and are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

Respectfully submitted,



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